UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,800	06/23/2000	David B. Agus	P1760R1	1759

7590 12/18/2002

Darlby & Darby P.C
805 Third Avenue
New York, NY 10022

EXAMINER
HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,800	AGUS ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 22-30* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed August 13, 2002 is acknowledged. Claims 11-20 were canceled. Claims 22-30 were added.

2. Claims 1-10 and 21-30 are pending.

Claim 10 is withdrawn from consideration. Claims 1-9 and 21-30 are examined on the merits.

Claim Rejections Withdrawn:

3. The rejection of claims 2, 4-5, and 20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the deposit information provided and the declaration.

4. The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by Curnow, Cancer Immunology Immunotherapy, Vol. 45, pages 210-215, 1997, as evidenced by Murphy et al., The American Society Textbook of Clinical Oncology, 1995, pages 126-127 is withdrawn in view of the cancellation of the claim.

5. The rejection of claim 16 under 35 U.S.C. 102(e) as being anticipated by Greene et al., US Patent 5,842,311, published October 20, 1998, or Arakawa et al., US Patent 5,783,186,

published July 21, 1998, as evidenced by Murphy et al., The American Society Textbook of Clinical Oncology, 1995, pages 126-127 withdrawn in view of the cancellation of claim 16.

6. The rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Hudziak et al., US Patent 5,725,856, published March 10, 1998, as evidenced by Murphy et al., The American Society Textbook of Clinical Oncology, 1995, pages 126-127, in view of in view of Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995 is withdrawn in view of the cancellation of the claim.

7. The rejection of claims 5 under 35 U.S.C. 103(a) as being anticipated by Greene et al., US Patent 5,842,311, published October 20, 1998, or Arakawa et al., US Patent 5,783,186, published July 21, 1998, as evidenced by Murphy et al., The American Society Textbook of Clinical Oncology, 1995, pages 126-127, in view of Fendly et al., Cancer Research, Vol. 50, pages 1550-1558, March 1, 1990, or Shepard et al., Journal of Clinical Immunology, Vol. 11, No. 9, pages 117-126, 1991 is withdrawn upon further consideration.

8. The rejection of claim 5 under 35 U.S.C. 102(e) as being anticipated by Curnow, Cancer Immunology Immunotherapy, Vol. 45, pages 210-215, 1997, as evidenced by Murphy et al., The American Society Textbook of Clinical Oncology, 1995, pages 126-127 in view of Fendly et al., Cancer Research, Vol. 50, pages 1550-1558, March 1, 1990, or Shepard et al., Journal of Clinical Immunology, Vol. 11, No. 9, pages 117-126, 1991 is withdrawn upon further consideration.

9. The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Hudziak et al., US Patent 5,725,856, published March 10, 1998, as evidenced by Murphy et al., The American Society Textbook of Clinical Oncology, 1995, pages 126-127, in view of in view of Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995, in view of Fendly et al., Cancer Research, Vol. 50, pages 1550-1558, March 1, 1990, or Shepard et al., Journal of Clinical Immunology, Vol. 11, No. 9, pages 117-126, 1991 is withdrawn upon further consideration.

10. The rejection of claims 5 under 35 U.S.C. 103(a) as being unpatentable over Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995, in view of Baselga et al., Oncology, Suppl. 2, March 1997 (Baselga I), or Baselga et al., Journal of Clinical Oncology, Vol. 14, No. 3, pages 737-744, March 1996 (Baselga II) in view of Fendly et al., Cancer Research, Vol. 50, pages 1550-1558, March 1, 1990, or Shepard et al., Journal of Clinical Immunology, Vol. 11, No. 9, pages 117-126, 1991 is withdrawn upon further consideration.

11. The rejection of claims 5 under 35 U.S.C. 103(a) as being unpatentable over Greene et al., US Patent 5,842,311, published October 20, 1998, or Arakawa et al., US Patent 5,783,186, published July 21, 1998, or Curnow, Cancer Immunology Immunotherapy, Vol. 45, pages 210-215, 1997, or Hudziak et al., US Patent 5,725,856, published March 10, 1998, or Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995, or Baselga et al., Oncology, Suppl. 2, March 1997 (Baselga I), or Baselga et al., Journal of Clinical Oncology, Vol. 14, No. 3, pages 737-744, March 1996 (Baselga II), all further in view of Fendly et al., Cancer Research, Vol. 50, pages 1550-1558, March 1, 1990, or Shepard et al., Journal of Clinical Immunology,

Vol. 11, No. 9, pages 117-126, 1991, all in view of Schlom, Molecular Foundations of Oncology, pages 95-134, 1991 is withdrawn upon further consideration.

Claim Rejections Maintained and New Grounds of Rejection:

12. Claims 4, 5 and 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 22 and 28 are indefinite for reciting having the biological characteristics of monoclonal antibody 2C4. This recitation may encompass any number of characteristics that have not been described in the specification.

13. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record. The basis for this rejection is that the specification, while being enabling for a method of treating prostate cancer in mammals by administering the anti-HER2 antibody 2C4, does not reasonably provide enablement for a method of treating a human having prostate cancer or androgen dependent prostate cancer wherein the method comprises administering any anti-ErbB2 antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

14. The rejection of claims 1 and 8 under 35 U.S.C. 102(e) as being anticipated by Greene et al., US Patent 5,842,311, published October 20, 1998, or Arakawa et al., US Patent 5,783,186, published July 21, 1998 are maintained for the reasons of record.

Greene et al., US Patent 5,842,311 teaches a method of treating a patient, which includes humans, by administering an antibody which binds ErbB2 and blocks activation of an ErbB receptor. Specifically, Greene teaches that the p185 oncogene (which is the same as ErbB2) has been found active in prostate adenocarcinoma, and further provides a method of using monoclonal antibodies which bind to ErbB2 to treat mammalian cancer tumors which express a translation of the neu oncogene on their surfaces (see column 3, line 50-column 5). The antibody of Greene et al. is not conjugated to a cytotoxic compound.

Arakawa et al., US Patent 5,842,311 teaches a method of treating a patient, which includes humans, by administering an antibody which binds ErbB2 and blocks activation of an ErbB receptor. Specifically, Arakawa teaches that the HER2 oncogene (which is the same as ErbB2) has been found active in prostate adenocarcinoma, and further provides a method of using monoclonal antibodies which bind to ErbB2 to treat mammalian cancer tumors which express HER2 on their surfaces (see column 6, lines 12-17, and lines 53-59). The antibody of Arakawa et al. is not conjugated to a cytotoxic compound.

15. The rejection of claims 1, 6, and 8-9 under 35 U.S.C. 102(b) as being anticipated by Curnow, Cancer Immunology Immunotherapy, Vol. 45, pages 210-215, 1997.

Curnow teaches a method of treating a human patient by administering an antibody which binds ErbB2 and blocks activation of an ErbB receptor (MDX-H210). The MDX-H210

antibody is not conjugated to a cytotoxic compound (see page 210, column 2) is maintained for the reasons of record.

16. The rejection of claims 1 and 8 under 35 U.S.C. 103(a) as being unpatentable over Hudziak et al., US Patent 5,725,856, published March 10, 1998, in view of Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995 is maintained for the reasons of record.

Hudziak et al., US Patent 5,842,311 teaches a method of treating a patient, which includes humans, by administering an antibody which binds ErbB2 and blocks activation of an ErbB receptor. Specifically, Hudziak teaches that the HER2 oncogene (which is the same as ErbB2) has been found active in numerous cancers, and further provides a method of using monoclonal antibodies which bind to ErbB2 to treat mammalian cancer tumors which express HER2 on their surfaces (see column 4, lines 27-31, column 6, lines 31-35, column 8, lines 27-30, column 10, lines 46-53, column 11, lines 32-40). The antibody of Hudziak et al. is not conjugated to a cytotoxic compound.

Hudziak et al. fails to teach that prostate cancer overexpresses HER2.

Zhi teaches that prostate cancer overexpresses HER2.

Therefore it would be prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use the method of treating HER2 overexpressing cancers on prostate cancer, and one would have been motivated to do so because prostate cancer overexpresses HER2 and anti-HER2 antibodies are an effective treatment for HER2 positive cancer, as taught by Hudziak et al.

17. The rejection of claims 1 and 8 under 35 U.S.C. 103(a) as being unpatentable over Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995, in view of Baselga et al., Oncology, Suppl. 2, March 1997 (Baselga I), or Baselga et al., Journal of Clinical Oncology, Vol. 14, No. 3, pages 737-744, March 1996 (Baselga II) is maintained for the reasons of record.

Zhi teaches a method of treating a prostate cancer cells, by administering an antibody which binds ErbB2 and blocks activation of an ErbB receptor in a prostate cancer which is androgen dependent. The antibody of Zhi is not conjugated to a cytotoxic compound. (see entire abstract)

Zhi fails to teach treatment of humans.

Baselga I teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor comprising administering an effective amount of an anti-ErbB2 antibody which binds the HER2 extracellular domain (page 46).

Baselga II teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor comprising administering an effective amount of an anti-ErbB2 antibody which binds the HER2 extracellular domain (see for example, abstract).

Therefore it would be prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use the method of treating HER2 overexpressing prostate cancer cells to treat humans having prostate cancer, and one would have been motivated to do so because anti-HER2 antibodies function in vitro to treat prostate cancer cells, as taught by Zhi, and further are an effective treatment for humans having a HER2 positive cancer, as taught by Baselga I and Baselga II.

18. The rejection of claims 1-4, and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al., US Patent 5,842,311, published October 20, 1998, or Arakawa et al., US Patent 5,783,186, published July 21, 1998, or Curnow, Cancer Immunology Immunotherapy, Vol. 45, pages 210-215, 1997, or Hudziak et al., US Patent 5,725,856, published March 10, 1998, or Zhi, Dissertation Abstracts, Vol. 55, No. 11, page 4738-B, May 1995, or Baselga et al., Oncology, Suppl. 2, March 1997 (Baselga I), or Baselga et al., Journal of Clinical Oncology, Vol. 14, No. 3, pages 737-744, March 1996 (Baselga II), all further in view of Fendly et al., Cancer Research, Vol. 50, pages 1550-1558, March 1, 1990, or Shepard et al., Journal of Clinical Immunology, Vol. 11, No. 9, pages 117-126, 1991, all in view of Schlom, Molecular Foundations of Oncology, pages 95-134, 1991 is maintained for the reasons of record.

Greene et al., or Arakawa et al., or Curnow, or Hudziak et al., or Zhi, or (Baselga I), or (Baselga II), or Fendly et al., or Shepard et al., teach as applied to claims 1-6, 8-9, 16 and 20 supra. Greene et al., or Arakawa et al., or Curnow, or Hudziak et al., or Zhi, or (Baselga I), or (Baselga II), or Fendly et al., or Shepard et al., fail to teach antibody fragments, including Fab's.

Schlom described the various known antibody modifications, including Fab's and that they provide the therapeutic advantage of reducing the host anti-Mab response (see pages 112-123).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Fab's of Schlom in the methods of Greene et al., or Arakawa et al., or Curnow, or Hudziak et al., or Zhi, or (Baselga I), or (Baselga II), or Fendly et al., or Shepard et al., and one would have been motivated to do so because they reduce the host anti-Mab response.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 16, 2002